SCBC

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Member of the
American Association
of Blood Banks,
the Florida Association
of Blood Banks and
America's Blood
Centers

September 9, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Dear Sir:

This letter regards the FDA proposal that blood establishments notify autologous donors of repeatedly reactive test results and supplemental test results.

In my opinion, this is an illogical and improper recommendation, since the order for drawing the autologous blood comes from the autologous donor's personal physician. The results should be given to the autologous donor's physician, who can provide medical follow-up and counseling. The autologous donor's physician also needs this information to know why his or her patient is receiving blood with a biohazard sticker.

Should the blood center notify the autologous donor of the positive test results, the recommendation for medical follow-up and counseling may not concur with the patient's personal physician. The correct procedure, which is most efficient and in the best interest of the donor, is to notify the ordering physician of the autologous blood of any abnormal laboratory results obtained on the autologous unit during processing. The ordering physician can then take care of the patient - even before surgery, if appropriate. This has been our policy for many years.

Respectfully submitted,

David E. Craig

David E. Craig, M.D.
Medical Director

DEC/kkr

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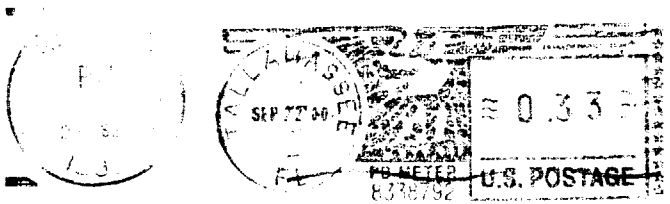

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